

REMARKS

Claims 1-22, 24 and 28-60 are pending in the application. Claims 25-27 are cancelled without prejudice to further prosecution. Applicant reserves the right to present these claims later in this case or in a related case. Claims 61-73 are added. New claims 61 – 73, as well as the amendments to the existing claims are supported in the original specification. Thus, no new matter has been added by way of this amendment.

A. The Claims Are Not Anticipated Under 35 U.S.C. 102(e) by Guirguis et al. Because Guirguis et al. Does Not Teach a Valve Having at Least One O-Ring Interposed Between the Chamber and the Reservoir, and Being Leak Resistant at the Recited Pressure

The Examiner rejected claims 1-5, 11, 13-17, 19-22, 24-29, 31, 33-40, 44-47, 49, and 51-56 under 35 U.S.C. Section 102(e) as allegedly being anticipated by U.S. Patent No. 6,277,646 (hereinafter “Guirguis”). In order to anticipate a claim, each and every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim. *Brown v. 3M*, 265 F.3d 1349, 60 USPQ2d 1375 (Fed. Cir. 2001). The reference must teach every aspect of the claimed invention either explicitly or impliedly. MPEP 2131.

The presently presented claims are not anticipated by Guirguis because Guirguis does not disclose or suggest a valve having at least one valve O-ring functionally interposed between said chamber and said reservoir, said valve being leak resistant between said chamber and said reservoir from about 0 PSI to about 50 PSI of internal pressure, as recited in the claims. The valve using O-rings utilized in the present invention prevents back-flow of used sample from the reservoir into the chamber. Additionally, this valve is able to retain its leak resistant properties under conditions of changing air pressure, for example, in the un-pressurized cargo hold of an aircraft without allowing leakage of sample from the reservoir back into the chamber. This preserves the sample remaining in the chamber in an uncontaminated state for future testing.

In contrast, Guirguis teaches either a “lance” valve with a penetrating member that breaks through a frangible bottom wall, or alternatively a stopper that plugs a hole (which the Examiner

incorrectly refers to as a valve). Neither of these types of valves prevent leakage of used sample back through the valve and into the chamber, especially under increased internal pressure conditions. Thus, Guirguis does not anticipate the presently claimed invention. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection.

B. The Claims Are Not Obvious Under 35 U.S.C. Section 103(a) in View of Guirguis and Various other References Because The References Cited by the Examiner Do Not, Either Alone or in Combination, Establish a *Prima Facie* Case of Obviousness for a Valve Having at Least One O-Ring Interposed Between the Chamber and the Reservoir, and Being Leak Resistant at the Recited Pressure

The Examiner rejected claims 6-8, 18, and 50 under 35 U.S.C. Section 103(a) as allegedly being unpatentable over Guirguis et al. in view of various other references. In order to establish a *prima facie* case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 2142.

Applicant amended claim 1 to recite a valve having at least one valve O-ring functionally interposed between said chamber and said reservoir, said valve being leak resistant between said chamber and said reservoir from about 0 PSI to about 50 PSI of internal pressure. None of the cited references, neither alone nor in combination with one another, teach or suggest a specimen collection device having a leak resistant valve having an O-ring that is leak resistant at about 0 PSI to about 50 PSI. The types of valves taught in the various references cannot maintain leak resistance at increased pressures and there is no motivation or suggestion provided by any of these references to use a valve of the type used in the instant invention. Therefore, Applicant respectfully submits that claim 1 as amended herein is not rendered obvious by any reference or combination of reference cited by the Examiner. For the same reasons described above, claims

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2-60 are not rendered obvious by any reference or combination of reference cited by the Examiner.

C. The Applicant will Submit a Terminal Disclaimer Under 37 CFR §1.321, if the Claims Are Otherwise Allowable in Their Present Form

The Examiner provisionally rejected claims 1-20 and 22-59 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-62 of copending Application No. 10/211,199.

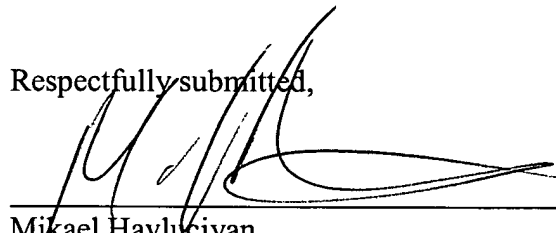
If the examiner determines that the claims in the present case are otherwise allowable in their present form, and if the claims of the cited co-pending application are allowed prior to the present claims, then the Applicant will submit a terminal disclaimer in the present case.

Conclusion

Applicant respectfully submits that the pending claims are now in condition for allowance and respectfully requests the same. If the Examiner has any questions regarding the foregoing, he is cordially invited to contact the undersigned so that any such matters may be promptly resolved. Please apply any charges or credits to deposit account 06-1050.

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Respectfully submitted,



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